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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,443

05/23/2006

Joachim Moormann

RO4245US (#90568)

2527

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/20/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,443	<b>Applicant(s)</b> MOORMANN ET AL.	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 16, 17, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-15, 18-20, 23-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/23/2006, 2/5/2007, 2/21/2007</u> .                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group II in the reply filed on 4/23/2009 is acknowledged. The traversal is on the ground(s) that the subject matter of the two groups presented for restriction are based on a single inventive concept. Applicants assert that the use of a medicament for treating a medical condition is closely related to the medicament itself or to the use of the active substance for the production of the medicament. This is not found persuasive because as discussed in the restriction requirement, the use of deoxyepanone for producing a medicament is known in the art as taught by Opitz et al. and thereby there is no special technical feature among the two groups.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections – 35 USC § 101***

Claims 7-15, 18-20 and 23-24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections – 35 USC § 112***

Claims 7-15, 18-20 and 23-24 provides for the use of deoxypeganine for treating schizophrenic psychosis, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For the sake of compact prosecution, claims 7-15 and 18-20 are being treated as a method for treating schizophrenic psychosis by administration of deoxypeganine, in the form of a free base or in the form of an acid addition salt, or of a derivative of deoxypeganine as long as said derivative is simultaneously an inhibitor of acetylcholinesterase and of monoamine oxidase.

***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 rejected under 35 U.S.C. 102(b) as being anticipated by Vonin et al. (Stvo Meditsina; Moscow, Russia; Vo. 91, No. 2 (Feb. 1991), pages 111-115).

Vonin et al. teach the treatment of schizophrenic patients with deoxypeganine (see Abstract, and page 115).

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-15, 18-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vonin et al. (Stvo Meditsina; Moscow, Russia; Vo. 91, No. 2 (Feb. 1991), pages 111-115) as applied to claim 7 above and in view of Opitz et al. (US Pg-Pub 2004/0132751)

Vonin et al. teaches the treatment of schizophrenic patients with deoxypeganine.

Vonin et al. does not teach a daily dose, the proportions of the active substance in a pharmaceutical, route of administration.

Opitz et al. teaches the use of deoxypeganine for the treatment of disorders of CNS, including psychiatric symptoms (paragraph 0001). It is taught that deoxypeganine can be used in its free base form or as an acid addition salt, with preferred salt being deoxypeganine hydrochloride and hydrobromide (paragraph 0015). Opitz et al. teaches that deoxypeganine is administered in a pharmaceutical preparation which contains the agent in proportions of from 0.1 to 90% by weight calculated as free deoxypeganine (paragraph 0016). The daily dose is in the range from 0.1 to 100 mg (paragraph 0017). It is taught that deoxypeganine can be administered orally, parenterally, as a depot medicament (paragraph 0031) and transdermally (paragraph 0031).

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Regarding the claims limitation of administration of the deoxypeganine being in the form of a derivative, as in claim 15, it is noted that the derivatives are structurally analogous to deoxypeganine and will have the same property of inhibiting both acetylcholinesterase and monoamine oxidase, absent a showing of unexpected results.

### ***Conclusion***

No claims are allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617